HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Quality System for General Sale Wholesale Distributors

IA-G0038-11
20 MAY 2026
This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

CONTENTS

1 SCOPE

The purpose of this document is to provide guidance to the general sale wholesale distribution sector on the minimum contents that are required in a quality management system.

2 INTRODUCTION

A quality management system consists of written procedures and forms which are approved and controlled by the company. These procedures and forms define how processes and activities in the daily operation of the business are performed and recorded. They ensure that each activity is performed to a standard prescribed method.

The Health Products Regulatory Authority (HPRA) has produced a set of written procedures and associated record forms with a view to providing guidance on the minimum requirements for those companies with the category 'medicinal products for general sale' only. These procedures may be incorporated into a company's quality system.

They may be used as an example of the content such procedures and record forms should contain. The procedures describe the course of action to be followed for each activity in a generalised manner. They must be amended to reflect the actual specific processes and steps undertaken at each premises to be incorporated into a company's quality system.

The procedures and forms are based on a hard-copy quality system only. They may need to be amended if the quality system is electronic. If a computerised system is used, the company must be able to demonstrate, through validation or verification studies, that the system is capable of achieving the desired results accurately, consistently and in a reproducible manner.

Each procedure should contain the following information:
- SOP title, number and version number
- Author and date of preparation
- Approver and date of approval
- Date of issue

3 INSPECTIONS

General sale wholesale distributors are subject to inspection by the HPRA to ensure compliance of the operation with the EU Guide to Good Distribution Practice. The frequency of an inspection is determined using a risk-based approach. This can result in an inspection frequency between a six-month and five-year cycle depending on the company's Good Distribution Practice (GDP) compliance record.

The frequency of inspection may now be reduced or increased depending on the following factors:

- Good compliance history
- Changes to operations
- Maintenance of the wholesale distribution authorisation
- Post-inspection follow-up

To support the risk-based approach to inspections, the HPRA has introduced a requirement for general sale wholesale distributors to complete an annual compliance assessment report. The annual compliance assessment report is used as a mechanism to monitor compliance outside the inspection process. The report should be submitted by 31 January each year. Failure to submit this report each year will directly affect the frequency of inspection.

The annual compliance assessment report can be found on the HPRA's website at www.hpra.ie.

4 STANDARD OPERATING PROCEDURE 01 – RESPONSIBLE PERSON

Introduction – The role of the Responsible Person

A Responsible Person (RP) must be designated at the site and named on the wholesale distribution authorisation (WDA). Any deputy who conducts the duties of the RP should also be named on the WDA.

Procedure

The responsibilities of the Responsible Person

The RP at the site should have sufficient knowledge to conduct the role. This should include a knowledge of the EU GDP Guidelines, the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 538 of 2007), as amended, and any supplementary guidance issued by the HPRA. The RP should be familiar with the wholesale activities conducted at the site and be continuously contactable.

The RP is responsible for:
- implementation and management of the quality system (including procedures and forms) at the site
- ensuring records are maintained and accurate
- overseeing training programmes of personnel
- coordinating recalls at the site
- dealing with customer complaints
- approval of suppliers
- approval of outsourced activities
- ensuring self-inspections are performed
- deciding the fate of returned, rejected, recalled or falsified medicinal products

The RP must also ensure that a record is kept if any of the duties described above are delegated to other personnel at the site.

Role Profile for the RP and Deputy RP

There should be a role profile in place describing the role and responsibilities for the RP. This should be signed and dated by the RP.

Where a Deputy RP (DRP) is appointed, there should be a role profile describing the responsibilities of this person and clarifying when the DRP is expected to act (e.g. during annual leave or sick leave of the RP).

5 STANDARD OPERATING PROCEDURE 02 – DOCUMENTATION CONTROL

Introduction – documentation control

A control system for GDP procedures should address the issue and distribution of procedures and retrieval of obsolete procedures. In this way, only the correct and most recent version of a procedure is in use.

Appendices

- Documentation Control Appendix 02/01 – SOP Index
- Documentation Control Appendix 02/02 – SOP Distribution List
- Documentation Control Appendix 02/03 – Revision History Log

Procedure

Standard Operating Procedures (SOPs) should describe the different operations which affect the quality of the products and the distribution activity. All forms associated with a particular procedure must also be controlled documents and to this effect they are included as appendices to the relevant procedure.

Each procedure has a title and unique number allocated to it. A list of procedures and their numbers is maintained in the SOP Index (Appendix 02/01).

Each procedure should include the company name and address.

Each procedure should have the following headings:
- introduction
- procedure

The following information must be recorded on the first page of each SOP:
- title of the SOP
- unique number of the SOP
- signature of the author of the SOP and the date of preparation
- version (issue) number of the SOP
- RP approval and the date of approval
- version number of the procedure
- date on which the procedure was issued

Creating a new SOP

As forms are included in the SOP as appendices, if a company creates or updates a form associated with a SOP, the SOP will also need to be amended to reflect the change.

Each form has a title and appendix number allocated to it.
Use the SOP Index (Appendix 02/01) to allocate the next consecutive number to the new procedure.

Complete the required information as per section 5.3 of this guide.

The RP is required to review and approve the procedure and must record this approval of the document by signing and dating the 'approved by' section on page 1 of the document.

All relevant personnel must be trained on the new procedure before it is issued, and this training must be recorded.

After all personnel have been trained, the date of issue on the first page of the procedure should be completed.

All procedures should be available to the relevant personnel at their site of operation.
Update the SOP Index (Appendix 02/01) to include the name of the new procedure, its number and version number.

Update the SOP Distribution List (Appendix 02/02) with the details of persons to whom copies have been issued.

Update the Revision History Log (Appendix 02/03) to include the new procedure and the reason for its creation.

Amend an existing SOP

As forms are included in the SOP as appendices, amending a form is considered as amending an existing SOP.

Use a copy of the existing procedure to record the changes required.

Update the information in the written by, version number and superseded number sections on page 1 of the procedure.

The RP must review and approve the procedure and must record this approval of the document by signing and dating the 'approved by' section on page 1 of the document.

The reason for the change to the document should be recorded in the Revision History Log (Appendix 02/03).

All relevant personnel must be trained on the amended procedure before it is issued, and this training must be recorded.

After all personnel have been trained, the date of issue on the first page of the procedure should be completed.

All procedures should be available to the relevant personnel at their site of operation.

Use the SOP Distribution List (Appendix 02/02) to ensure that all copies of the previous version of the procedure are withdrawn from those personnel listed in the SOP Index before copies of the new procedure are issued. Record the removal of old copies and the issue of new copies to each relevant person. The date of removal and issue should also be recorded.

Record the new version number of the procedure on the SOP Index (Appendix 02/01).

All obsolete copies of the procedure/form should be destroyed. However, the master copy (i.e. the copy with the original signatures) of the obsolete version should be marked 'obsolete' and kept on file.

Maintenance of records

All documentation and records relating to the distribution activity (including training records, obsolete procedures, etc.) must be maintained for a minimum of five years.

Documentation should be reviewed on a regular basis to ensure that it is still up to date, and a record of this review should be maintained.

All entries to GDP documentation should be legible and written in a manner to ensure against fading, etc.

Overwriting, use of ditto marks, correction fluids or pencil should not be allowed.
Adjustments to an incorrect entry/record should only be made by drawing a line through the incorrect entry and writing the correct entry. The adjustment must be initialled and dated by the person correcting the entry.

All records should be signed and dated by the person carrying out the activity.

APPENDICES TO DOCUMENTATION CONTROL PROCEDURE

Appendix 02/01 – SOP Index

SOP no.	Title	Version no.

Appendix 02/02 – SOP Distribution List

SOP no.	Title	Version no.	Withdrawn from/date	New version issued to/date

Appendix 02/03 – Revision History Log

SOP no.	Title	Version no.	Reason for change

6 STANDARD OPERATING PROCEDURE 03 – DEVIATIONS

Introduction – Deviations

Deviations are non-conformances with GDP, regulations or approved company procedures. A procedure needs to be in place outlining the process for identifying, documenting, investigating and closing deviations. The RP should be notified of deviations and an assessment performed to determine product quality implications and/or impact on the quality system. Appropriate corrective and preventative actions need to be taken to correct and prevent deviations in line with quality risk management principles. This process should be completed within a justified time period, e.g. 30 days.

Appendices

- Deviation Appendix 03/01 – Deviation Log
- Deviations Appendix 03/02 – Deviation Form

Procedure

Deviations

The RP should be notified of any deviations that occur during wholesale operations or any deviations that the company plans to make from its approved procedures. Appendix 03/01 – Deviation Log, and Section I of Appendix 03/02 – Deviation Form, should be used to immediately record a description of the deviation. The deviation should be given the next sequential number in the Appendix 03/01 – Deviation Log. This log should be kept up to date as each section of the Appendix 03/02 – Deviation Form is completed.

The RP should conduct an initial assessment of the impact of the deviation on product quality and/or on the quality management system. The company should consider whether the deviation has occurred previously, and the potential impact of this. The deviation should be classified by the company based on the initial assessment. This classification should determine the level of detail required in the subsequent sections. The company should include a descriptor and examples for each classification to aid the decision-making process.

For example:

Classification	Descriptor	Examples may include
Critical	Presenting a significant risk to product quality	Failure to quarantine products not suitable for sale
Major	Potential to compromise product quality	Temperature deviations, incorrect documentation, inadequate checks on the authority of customers and/or suppliers, recurring minor deviations

Classification	Descriptor	Examples may include
Minor	Deviation which is considered significant but not critical or major	Isolated incidents of incomplete documentation, loss of electricity

Section I of Appendix 03/02 – Deviation Form should be used to document a summary of the initial assessment and the resultant classification of the deficiency.

Investigation

The company should conduct an investigation into the deviation and aim to identify the root cause of the deviation. The principles of quality risk management should be considered and a decision taken as to whether a risk assessment is required. Section II of Appendix 03/02 – Deviation Form should be used to document this information.

Corrective and preventative actions (CAPA)

Based on the investigation and the identified root cause the company should propose corrective and/or preventative actions to mitigate any potential risks identified following the deviation. The RP should be aware of all proposed corrective and preventative actions. Each action should be assigned a member of staff who is given responsibility and a target date for completion. This should be documented in Section III of Appendix 03/02 – Deviation Form.

Once all actions are implemented, the company should evaluate their effectiveness. This is to ensure that actions will be successful in preventing future deviations. The effectiveness check may need to be completed a couple of weeks or months after the actions have been implemented. Section III of Appendix 03/02 – Deviation Form should be used to document this. If the RP deems that the corrective and preventative actions are effective, the deviation can be closed.

If corrective and preventative actions are not deemed effective, the RP should re-evaluate the deviation and investigation. Further corrective and preventative actions may need to be implemented, and additional documentation appended to the form. The deviation should not be closed until satisfactory actions have been implemented and deemed effective.

Close-out

Once a deviation is ready to be closed, Appendix 03/01 – Deviation Log and Section IV of Appendix 03/02 – Deviation Form should be updated accordingly. The RP should document any closing comments at this time.

The company should ensure that all documentation relating to the deviation is stored in an easily retrievable manner.

The company should ensure that deviations are closed out in within a justified time period, e.g. 30 days.

APPENDIX TO DEVIATION PROCEDURE

Appendix 03/01 – Deviation Log

Opened by and date	Deviation number	Description of deviation	Classification (critical, major or minor)	Target date for completion of CAPA	Date all CAPA completed	Date effectiveness checks on CAPA completed	Closed by and date

Appendix 03/02 – Deviation Form

Section I

Deviation number:

Description of deviation:	
☐ Planned	☐ Unplanned

Assessment of the potential risks associated with deviations and impact on GDP compliance	
Previous occurrence of deviation	☐ Yes ☐ No
If yes, provide a brief description of previous occurrences:	

Classification of deviation: ☐ Critical ☐ Major ☐ Minor	
Signed by (RP):	Date:

Section II – Investigation

Investigation (including root cause analysis)
Identified root cause for deviation

Signed by (RP):	Date:

Risk assessment required?	☐ Yes ☐ No
If yes, is the risk assessment complete and attached to the deviation form?	☐ Yes
If no, provide a brief justification for not completing the risk assessment.	
Approved by (RP):	Date:

Section III – Corrective and preventative actions

Corrective and preventative action(s) required	Assigned to:	Target date for completion:	Completed by and date:	Approved by (RP) and date:

Evaluation of the effectiveness of the corrective and preventative actions	
Are implemented CAPA effective?	
Approved by (RP):	Date:
If No, has the deviation and investigation been re-evaluated and supporting documentation to close the deviation been attached to the deviation form?	☐ Yes ☐ No
Approved by (RP):	Date:

Section IV – Close-out

Close-out comments:	

Closed by (RP):	
Date closed:	

7 STANDARD OPERATING PROCEDURE 04 – CHANGE CONTROL

Introduction – Change control

A change control system should be in place to identify, document and assess changes which may impact on compliance with GDP. These may include changes to key personnel, premises, equipment, and operations at the site.

Appendices

- Change Control Appendix 04/01 – Change Control Log
- Change Control Appendix 04/02 – Change Control Form

Procedure

Change control

Once a proposed change which may impact compliance with GDP is identified within the company, the change control should be initiated. Such changes may include, for example, a change to key personnel such as the RP or DRP, relocation of the medicinal product storage area, installation of a heating or cooling system or a change in a service provider such as a logistics company. These changes must be conducted in a controlled manner.

The RP should be notified and Appendix 04/01 – Change Control Log and Section I of Appendix 04/02 – Change Control Form should be used to record the change control. The change control should be given the next sequential number from the Appendix 04/01 – Change Control Log. This log should be kept up to date as each step of the change control is completed.

The RP should assess the impact of the change on the company's GDP activities. The assessment process should consider areas such as processes, equipment, personnel, training, validation, quality systems and regulatory implications. The results of this assessment should be documented in Section I of Appendix 04/02 – Change Control Form and all areas impacted should be listed.

The principles of quality risk management should be part of the change control process. The RP should consider whether a risk assessment is required prior to approving the proposed change. This decision should be documented on Appendix 04/02 – Change Control Form. If a risk assessment is to be performed it should be documented, and a copy kept with the Appendix 04/02 – Change Control Form.

The relevant managerial representative of the area of the operation impacted by the proposed change should also approve the change. Following this, the RP should then decide whether to the proposed change is acceptable or rejected.

Accepting a proposed change

If the change is accepted, the company should propose actions in order to mitigate any potential risks identified and to effectively implement the change. Each action should be assigned a member of staff who is given responsibility and a target date for completion. This should be documented in Section II of Appendix 04/02 – Change Control Form.

Once all actions are completed and the change is implemented, the company should evaluate the effectiveness of the change. Section III of Appendix 04/02 – Change Control Form should be used to document the effectiveness of the actions taken. If these are deemed appropriate, then the change control can be closed and Appendix 04/01 – Change Control Log and Section IV of Appendix 04/02 – Change Control Form should be updated accordingly.

Rejecting a proposed change

If the change is rejected the company should inform the relevant personnel and close the change control. Appendix 04/01 – Change Control Log and Section IV of Appendix 04/02 – Change Control Form should be updated accordingly.

The company should ensure that change controls are closed out within a justified time period.

APPENDIX TO CHANGE CONTROL PROCEDURE

Appendix 04/01 – Change Control Log

Change control number	Opened by and date	Description of proposed change	Target date for completion of actions	Date all actions completed	Date effectiveness checks completed	Closed by and date

Appendix 04/02 – Change Control Form

Section I

Change control number:

Description of proposed change

Assessment of the proposed change and its impact on GDP activities

Risk assessment required?	☐ Yes ☐ No
If yes, is the risk assessment complete and attached to change control form?	☐ Yes
If no, provide a brief justification for not completing the risk assessment.	
Approved by (RP):	Date:

Decision of RP on proposed change:	☐ Approved ☐ Rejected
Signed by (Section representative):	Date:
Signed by (RP):	Date:

Section II

Action required:	Assigned to:	Target date for completion:	Completed by and date:	Approved by (RP) and Date:

Section III

Evaluation of the effectiveness of the corrective and preventative actions	
Are implemented CAPA effective?	☐ Yes ☐ No
Approved by (RP):	Date:
If no, has the deviation and investigation been re-evaluated and supporting documentation to close the deviation been attached to the deviation form?	☐ Yes ☐ No
Approved by (RP):	Date:

Section IV

Close-out comments:	
Closed by (RP):	
Date closed:	

8 STANDARD OPERATING PROCEDURE 05 – MANAGEMENT REVIEW AND MONITORING

Introduction – Management review and monitoring

The role of management within the wholesale operation is emphasised within the legislation. It is important that management is involved, provides adequate resources and maintains oversight of GDP compliance.

Procedure

Management should have a formal process for reviewing the quality system on a periodic basis. The frequency of these reviews should be determined on a risk basis and be documented in the company's procedure. It should be performed at least annually.

The personnel present at these meetings should include the RP and senior management personnel.

The review should include:
- measurement of the achievement of quality system objectives
- assessment of performance indicators that can be used to monitor the effectiveness of processes within the quality system, such as complaints, returns, deviations, change control, changes to processes, feedback on outsourced activities, self-assessment process such as self-inspection and risk assessments and external assessments such as inspections, findings and customer audits
- emerging regulations, guidance and quality issues that can impact the quality management system
- innovations that might enhance the quality system
- changes in the business environment and objectives

The outcome of the management review should be documented following the meeting within a justified time period. This should include details of all personnel who attended the review, the topics discussed and the associated outcomes. The outcome of the management review should be communicated internally to all relevant personnel.

9 STANDARD OPERATING PROCEDURE 06 – QUALITY RISK MANAGEMENT

Introduction – Quality risk management

Quality risk management (QRM) is the systemic process for the assessment, control, communication and review of risks to the quality of the medicinal product. It is a valuable component of the quality system and can be applied proactively and retrospectively. The level of detail in the risk management should be reflective of the level of risk to the quality of the product.

Quality risk management should be an integrated part of the quality management system such as the change control procedure, the deviation procedure and the returns procedure of a company.

Appendices

Quality Risk Management Appendix 06/01 – Risk assessment form

Procedure

Risk assessment

If any member of staff identifies a potential risk to the quality of medicinal products, the RP should be informed. Potential risks to the quality of medicinal products could include an increase in the operations at the site, the introduction of new product to the site or an increased incidence of theft in the local area.

Section I of Appendix 06/01 – Risk Assessment Form should be used to document a summary of the potential risk to quality and an assessment of the risk. The assessment of the potential impact of the risk on the quality of medicinal products should consider the likelihood of the risk occurring at the site and the severity of the impact on product quality, security and traceability. The evaluation should be based on scientific knowledge, reasons and experience and should ultimately link to the protection of the patient.

Based on the assessment of the risk the RP should decide whether corrective and/or preventative actions are required to mitigate the risk. This decision should be documented in Section I Appendix 06/01 – Risk Assessment Form.

For more information on risk management and performing risk assessments, consult the ICH Harmonised Tripartite Guideline entitled 'Quality Risk Management – Q9'. This is available to download on the ICH website.

Corrective and preventative actions

If necessary, the company should propose corrective and/or preventative actions to mitigate any potential risks identified. The RP should be aware of all proposed corrective and preventative actions. Each action should be assigned a member of staff who is given responsibility and a target date for completion. This should be documented in Section II of Appendix 06/01 – Risk Assessment Form.

Once all actions are implemented, the company should evaluate their effectiveness. This effectiveness check may need to be completed following a justified period of time after the actions have been implemented. Section II of Appendix 06/01 – Risk Assessment Form should be used to document this. If the RP deems that the corrective and preventative actions are effective, the risk assessment can be closed.

If corrective and preventative actions are not deemed effective, the RP should re-evaluate the risk. Further corrective and presentation actions may need to be implemented, and additional documentation appended to the form. The risk assessment should not be closed until satisfactory actions have been implemented and deemed effective.

Close-out

Once a risk assessment can be closed, Section III of Appendix 06/01 – Risk Assessment Form should be updated accordingly. The RP should document any closing comments at this time.

The company should ensure that all documentation relating to the risk assessment is stored in an easily retrievable manner.

The company should ensure that risk assessments are closed out within a justified time period.

APPENDIX TO QUALITY RISK MANAGEMENT PROCEDURE

Appendix 06/01 – Risk Assessment Form

Section I

Risk assessment number:

Description of the potential risk to quality:

Assessment of the potential risk to quality
Consideration should be given to: - the likelihood of the risk occurring - the severity of the impact on product quality - the severity of the impact on product security - the severity of the impact on product traceability

CAPA required to mitigate risk	☐ Yes ☐ No

If yes, confirm that section II of the form will be completed.	☐ Confirmed
If no, provide a brief justification for not implementing corrective and/or preventative actions to mitigate the risk	
Approved by (RP):	Date:

Section II – Corrective and preventative actions

Corrective and preventative action(s) required to control the risk	Assigned to:	Target date for completion:	Completed by and date:	Approved by (RP) and date:

Evaluation of the effectiveness of the corrective and preventative actions	
Are implemented CAPA effective?	☐ Yes ☐ No
Approved by (RP):	Date:
If no, has the risk been re-evaluated and supporting documentation to close the risk assessment been attached to the risk assessment form?	☐ Yes ☐ No
Approved by (RP):	Date:

Section III – Close-out

Close-out comments:	
Closed by (RP):	
Date closed:	

10 STANDARD OPERATING PROCEDURE 07 – TRAINING

Introduction – Training

Key personnel involved in the distribution of medicinal products should have the appropriate ability and training to guarantee that medicinal products are properly stored and handled.

Appendices

Training Appendix 07/01 – Training record form

Procedure

Employee training

The RP must ensure that all personnel are qualified to perform their duties satisfactorily. This includes all staff who order medicinal products, receive medicinal products, store and pick and dispatch/transport the medicinal products.

All new personnel must undergo induction training in the principles of GDP prior to commencing GDP activities. This training must be recorded on the Training Record Form (Appendix 07/01).

Booster (refresher) GDP training should be provided to all relevant staff at least annually.

All personnel should be trained in relation to the duties assigned to them before they commence any activities. Personnel should be adequately trained in all SOPs that are relevant to their area of operation. Use the Training Record Form (Appendix 07/01) to highlight the SOPs in which each employee needs to be trained.

All training must be adequately documented using the Training Record Form (Appendix 07/01). The following information must be recorded:

- employee name, date of commencement of employment and job description
- type of training (e.g. GDP induction or booster training)
- title and version number of the written procedure
- date of training
- duration of the training
- signature of the trainee
- signature of the trainer

Personnel records must include details of any relevant experience and relevant educational qualifications.

Training records for the RP and Deputy RP

There should be a role profile in place describing the role and responsibilities for the RP, signed and dated by the RP.

Where a Deputy RP is appointed, there should be a role profile describing the responsibilities of this person and clarifying when the Deputy RP is expected to act (e.g. during annual leave or sick leave of the RP).

Where the RP approves the written procedures and their signature is recorded on the front of each SOP, this can be taken as evidence that the RP has knowledge and is trained in those written procedures and there is no need for separate training records for the RP.

Where the Deputy RP writes a procedure and their signature is recorded on the front of each SOP, this can be taken as evidence that the Deputy RP has knowledge and is trained in those written procedures and there is no need for separate training records for the Deputy RP for these procedures.

The Deputy RP will require training on any written procedures he/she did not write.

APPENDIX TO TRAINING PROCEDURE

Appendix 07/01 – Training Record Form

Employee name:

Job description:

Type of training (induction or booster):

Duration of training:

SOP no.	Title	Required by employee (Y/N)	Version no.
N/A	Principles of GDP	Y	N/A

Trainee signature: Date:

Trainer signature: Date:

11 STANDARD OPERATING PROCEDURE 08 – CLEANING PROCEDURE

Introduction – Cleaning Procedure

Premises and storage facilities should be suitable and adequate to ensure proper storage of medicinal products. Storage facilities should be clean and free from litter and dust. Cleaning equipment should be chosen and used in order not to be a source of contamination.

The storage of food, drink or medication for personal use in the storage areas is prohibited.

Rest, wash and refreshment rooms for employees should be adequately separated from the storage areas.

Appendices

Cleaning Procedure Appendix 08/01 - Cleaning Log

Procedure

All areas in which medicinal products are stored or held (i.e. goods inwards and receipt areas, storage areas, quarantine areas and dispatch areas and delivery vehicles) should be cleaned on an on-going basis. The company should execute a cleaning regime as required (i.e. on a daily, weekly, monthly and annual basis).

Examples of daily cleaning include:
- All rubbish and non-essential product packaging and wrapping should be removed from the warehouse and disposed of.
- All waste bins should be emptied and fresh bin liners put in place.
- Receiving, dispatch areas and aisle ways should be kept clear of cluster and swept clean.

Examples of monthly cleaning include:
- The main floor areas of the warehouse should be washed with an appropriate cleaning agent.
- Pallets stored at ground level should be moved to facilitate cleaning.
- Tables and benches in the receiving and dispatch areas should be cleaned.

Examples of annual cleaning include cleaning walls, high-level areas, unit heaters and light fittings.

All cleaning should be recorded in the Cleaning Log (Appendix 08/01). This should include a description of the area cleaned and cleaning agents used. The person performing the cleaning should sign and date this log. The cleaning should be checked by a second person, and this check should be recorded in the log.

Cleaning records should be reviewed on a regular basis and this review should be recorded on the Cleaning Log.

APPENDIX TO CLEANING PROCEDURE

Appendix 08/01 – Cleaning Log

Type of cleaning: ☐ Daily ☐ Monthly ☐ Annual

Date	Cleaning carried out	Area cleaned	Cleaning agent used	Performed by	Checked by

Reviewed by: Date:

12 STANDARD OPERATING PROCEDURE 09 – PEST CONTROL PROGRAMME

Introduction – Pest control programme

Premises and facilities should be designed and equipped so as to afford protection against the entry of insects, rodents or other animals.

Procedure

A preventative pest control programme must be in place.

Where the company employs an external company to provide the preventative pest control programme, the requirements detailed in this guide under SOP 18 'Outsourced Activities' must be followed.

Where the company performs its own pest control monitoring, a record of the checks performed and biocidal products used should be maintained.

Bait boxes should be located at ground level and in areas of the warehouse where the ingress of pests may be possible. These boxes should be numbered.

Where necessary, electrical fly killers should be installed.

A bait map should be maintained identifying the location of bait boxes and electrical fly killers on site. This map should be approved by the company (i.e. signed and dated by the RP).

Any subsequent changes to the locations of bait points should be marked on the bait map and signed and dated by the company.

There should be regular checks of the bait boxes conducted. The number of visits should be documented within the service contract/agreement. A record of the checks should be maintained.

The company should review reports issued by the pest control company and record this review.

If a member of staff identifies infestation on site, the manager or RP should be notified. The external pest control company should be contacted to address the issue.

Where the pest control contractor recommends the company performs corrective actions to address certain issues, the company should record completion of these corrective actions. The completion of these actions should be signed off by the RP.

13 STANDARD OPERATING PROCEDURE 10 – RECEIPT OF MEDICINAL PRODUCTS

Introduction – Receipt of medicinal products

This procedure outlines the steps to be followed when medicinal products are received. It ensures that the correct products are received, that they originate from an approved supplier and that they have not been damaged or altered during transportation. See in this guide SOP 20 'Management of Falsified Medicinal Products'.

Receiving and dispatch areas should protect products from prevailing weather conditions. There should be adequate separation between receipt and dispatch areas and general storage areas.

Appendices

Receipt of Medicinal Products Appendix 10/01 – Quarantine Log

Procedure

Goods inwards checking

Medicinal products must only be received from approved suppliers whose authority to supply such items has been verified by the company. See in this guide SOP 11 'Establishing the Authority of Suppliers to Supply Medicinal Products'.

Use the 'Approved Supplier List' (Appendix 11/01) to check that the products have been supplied by the correct supplier.

Notify the RP if products are received from a supplier not listed on Appendix 11/01.

Check whether the product and batch number is listed on the Falsified Medicinal Product Notification Log (Appendix 20/01) (See in this guide SOP 20 'Management of Falsified Medicinal Products'). Contact the RP immediately if the product is listed.

Incoming goods should be checked for any sign of physical damage. No action is required where damage is superficial and does not affect product packaging. Where product is damaged, see in this guide section 13.3.2 Non-conforming products.
Using the documentation received with the consignment from the supplier, check that the product name, strength and quantity is consistent with the actual products physically received. If a batch number is specified on the supplier's documentation, this should also be physically checked, and the check recorded. The person conducting this check should sign or initial the record and date it.

Differences should be reported immediately to the warehouse supervisor/manager and the RP and noted on the documentation received from the supplier. See in this guide section 13.3.2 Non-conforming products.

The products received should be checked against the company's original order placed with the supplier. This can be done, for example, by using the purchase order (PO) generated by the company. The product name, strength and quantity received should be checked to ensure it complies with those listed on the PO, and the check recorded. The person conducting the check should sign or initial the document and date it.

Any differences should be reported to the warehouse supervisor/manager.

One pack of each batch of each product received must be examined to ensure that the Product Authorisation (PA) number is visible on the pack. A PA number is in the format PAxxx/xxx/xxx. A medicinal product that does not bear a PA number should not be accepted. Record this PA number check. The person conducting the check should sign or initial and date the relevant documentation.

One pack from each batch of product received should be examined to check the expiry date. Products should only be accepted if they have an acceptable shelf life remaining. Companies should set their own acceptance criteria for shelf-life limits.

Once products have been receipted at goods inwards and where applicable have been entered on the company's inventory management system, they should be moved to an allocated storage area.

Medicinal products should normally be stored apart from other goods and under the conditions specified by the manufacturer. See in this guide SOP 13 'Storage of Medicinal Products' and SOP 12 'Temperature Mapping and Monitoring'.

Non-conforming products

Where the products do not match what was ordered (e.g. incorrect product, incorrect quantity, incorrect or missing PA number, incorrect batch number) or they do not have an acceptable shelf life remaining, they should be placed in quarantine until a decision is made as to their disposition.

Damaged goods should be held in quarantine pending an investigation and credit agreement with the supplier.

All products held in quarantine should be recorded on the Quarantine Log (Appendix 10/01). When a decision has been made and the products are removed from quarantine (either to be sent back to the supplier, or to be rejected or to be made available as saleable stock) this must be recorded on the Quarantine Log by the RP.

If the product is rejected, it must be transferred to the 'reject area' and recorded in Appendix 13/01 Rejected Products Log.

The decision to enter products into saleable stock must be made by the RP and justified by a written record, which is maintained.

If the product is entered into saleable stock, it must be entered onto the inventory management system.

APPENDIX TO MEDICINAL PRODUCTS PROCEDURE

Appendix 10/01 – Quarantine Log

Quarantined by and date	Product name and authorisation number	Product strength	Batch no.	Quantity	Reason	Removed by and date	Disposition by RP (S/R/D)*

* S (Saleable), R (Returned), D (Destroyed)

14 STANDARD OPERATING PROCEDURE 11 – ESTABLISHING THE AUTHORITY OF SUPPLIERS TO SUPPLY MEDICINAL PRODUCTS

Introduction – establishing the authority of suppliers to supply medicinal products

Medicinal products should only be purchased from authorised suppliers. Prior to purchase of any medicinal product the authority of the supplier to supply medicinal products must be established. It is the responsibility of the wholesaler to establish this and to obtain appropriate documentary evidence. The wholesaler is responsible for approving both the physical and financial supplier of medicinal product.

A robust system for approval of new medicinal product suppliers is a key component of the wholesaler's strategy against falsified medicines. In addition to establishing the authority of the supplier, wholesalers should also reassure themselves that previous stages in the supply chain are sufficiently robust to ensure the legitimacy of the medicinal products concerned. This includes having knowledge of the supply chain involved for the products and being aware of all parties involved (i.e. any arrangements between the manufacturers and suppliers – see paragraph 3 under section 14.3.1 of this guide).

Suspicious or unusual issues with respect to the sourcing of medicinal products should be reported to the HPRA.

Appendices

Establishing the authority of suppliers to supply medicinal products Appendix 11/01 – Approved Suppliers List

Procedure

New suppliers

Before entering into business with a new medicinal product supplier, request a copy of their wholesaler's authorisation or manufacturer's authorisation and a copy of the most recently issued GDP or Good Manufacturing Practice (GMP) certificate. Use the HPRA or the EudraGMDP website to check the status of the supplier against the list of authorised wholesalers or manufacturers and obtain a printout of the web page. It is important to review the content and detail of each authorisation including the supplier's addresses and also verify that the supplier is authorised to supply the authorised categories of medicinal products.

The non-compliance report on EudraGMDP should be reviewed to ensure the supplier wholesale distribution authorisation has not been revoked by the competent authority.

Use the Approved Suppliers List (Appendix 11/01) to record the details of the supplier, the products they intend to supply and the required storage conditions of these products.

If the supplier uses a third party on their behalf or if other parties are involved in the supply chain of their products, record details of these arrangements on Appendix 11/01.

The RP must be involved in the approval of new suppliers.

A copy of this list should be provided to personnel at goods inwards so that they can perform a check on receipt of products as required in SOP 10 'Receipt of Medicinal Products'.

Medicinal products should only be ordered from suppliers for whom an authorisation and certificate have been received.

Existing suppliers

At least annually, the authorisation of all suppliers should be reviewed.

This can be done by checking the status of the supplier against the list of authorised wholesalers on the HPRA website and obtaining a printout.

- If it is found that a supplier is no longer listed as an authorised wholesaler, notify the RP.
- If it is determined that a supplier is no longer authorised, they must be removed from the Approved Suppliers List (Appendix 11/01). An updated copy of the list should be given to goods inwards personnel.
- No medicinal products should be received from that supplier.

APPENDIX TO PROCEDURE FOR ESTABLISHING THE AUTHORITY OF SUPPLIERS TO SUPPLY MEDICINAL PRODUCTS

Appendix 11/01 – Approved Suppliers List

Supplier name:
Supplier address:
Other supply chain parties:

Product description:	**Required storage conditions:**

Wholesale distribution authorisation / manufacturing authorisation	☐ Yes	☐ No
GDP certificate/GMP certificate	☐ Yes	☐ No
Independent verification on HPRA or EudraGMDP website	☐ Yes	☐ No

Supplier approved by (RP): Date:

15 STANDARD OPERATING PROCEDURE 12 – TEMPERATURE MAPPING AND MONITORING

Introduction – Temperature mapping and monitoring

Medicinal products should only be stored under the conditions specified by the manufacturer. Storage conditions are normally specified on the containers, for example, 'Keep the container in the outer carton', 'Keep the container tightly closed', 'Do not store above 25°C' or 'Do not refrigerate'.

An initial temperature mapping exercise or risk assessment of the storage area must be performed and documented. Continuous temperature monitoring probes should be located according to the results of the mapping exercise or risk assessment to ensure that the appropriate conditions are maintained. This applies to all areas where medicinal products are stored (e.g. bulk storage, pick-face, quarantine and returns areas). At a minimum, a maximum/minimum type thermometer should be used. The maximum and minimum temperatures should be recorded every day and the thermometer reset.

Products should not be stored in close proximity to unit heaters or air conditioning units.

Appendices

Temperature Monitoring Appendix 12/01 – Temperature Monitoring Record Form

Procedure

Temperature mapping or risk assessment of storage area

Temperature probes used to continuously monitor temperatures in the storage area should be located in the 'worst-case scenario' areas that experience the extremes of fluctuations, i.e. where they would be expected to observe a high or low temperature first.

The use of a temperature mapping study should be employed to identify suitable monitoring locations. For areas less than a few square meters which are at room temperature, a risk assessment of the storage area can be conducted instead of a full mapping study.
This risk assessment should consider potential risks to temperature such as skylights, proximity to doors, temperature control systems (i.e. heaters, coolers) and storage at high levels. Temperature monitoring data for the storage area should also be taken into consideration. This risk assessment should be documented and approved by the RP. Based on the results of the risk assessment the company should identify and document suitable locations for the temperature monitoring probes. The RP should document their approval of this decision.

The temperature mapping study or risk assessment of the storage area should be repeated after every significant modification to the premises or changes to the temperature control system.

For more detailed information on temperature monitoring and mapping requirements, refer to the HPRA document entitled 'Guide to Control and Monitoring of Storage and Transportation Temperature Conditions for Medicinal Products and Active Substances', on the HPRA website at www.hpra.ie.

Daily monitoring

Temperature probes should be located in the 'worst-case scenario'- where they would be expected to observe a high or low temperature.

Once a day record the maximum and minimum temperature reading on the monitoring device in each area where medicinal products are stored. Record the readings on the Temperature Monitoring Record Form (Appendix 12/01).

There should be a separate form for each storage area and the area should be indicated on the form.

- The person taking the reading should sign the form.
- The device should be reset after each reading.
- The RP should review the records on a monthly basis and record this review on Appendix 12/01.
- The company should set limits for the temperature at which medicinal products are stored based on the storage conditions listed in the Approved Suppliers List (Appendix 11/01). In general, the temperatures should be maintained between 8°C and 25°C.
- The RP must be informed if the temperature goes below 8°C or exceeds 25°C.
- The RP should investigate the cause of this temperature excursion, and the temperature should be monitored more frequently on such occasions.
- The RP should open a deviation and record the investigation on the Deviation Form (Appendix 03/02). The associated deviation number should be recorded on Appendix 12/01.
- The manufacturer of the product should be consulted to ascertain the effect of any excursions from the labelled storage conditions on the quality of the product. Supporting documents should be maintained if necessary.

If there is uncertainty regarding the quality of a product due to the effect of a temperature excursion then it should be removed to the quarantine area until a decision is made on its disposition. It should be recorded in the Quarantine Log (Appendix 10/01).

In times of extreme temperatures (summer and winter), it may be necessary to monitor the temperature more frequently.

If excursions occur frequently, then it indicates that the storage area is not suitable for storing medicinal products. The products should be transferred to a more suitable area.

Calibration of temperature probes

The temperature-monitoring device should be recalibrated as recommended by the manufacturer of the device or the calibration provider. This is usually on an annual basis. Alternatively, new probes may be purchased to replace the older ones.

The calibration should be traceable to a national standard.

Normally the device must be returned to the supplier for this work to be carried out. Back-up devices must be put in place while this is being done.

There should be a copy of the service agreement with the calibration service provider maintained on file and this should be approved by the RP.

Where a back-up thermometer is used to replace a device being calibrated, this should be documented on the Temperature Monitoring Record (Appendix 12/01) along with the date.

It must be ensured that the back-up device itself is within its valid calibration period.

If on return of the original device from the calibration service provider, it is put back in place, this must be documented on Appendix 12/01.

The calibration certificates should be on file. These should be reviewed by the RP to ensure the probes were calibrated to cover the range of temperatures over which the device is used.
A three-point calibration is recommended (for example at 0°C, at 15°C and at 30°C). The review should be documented by signing and dating each certificate.

If it is found that the device did not pass the calibration, it must not be put back into use but be removed and either disposed of or repaired.

APPENDIX TO TEMPERATURE MONITORING PROCEDURE

Appendix 12/01 – Temperature Monitoring Record

Date	Max. temp. °C	Min. temp. °C	Performed by

Note: Temperatures of 25°C or higher and 8°C or lower must be notified to RP.

Record reviewed by: Date:

Details of temperature excursions and investigations:

Date	Deviation number	RP review and approval

16 STANDARD OPERATING PROCEDURE 13 – STORAGE OF MEDICINAL PRODUCTS

Introduction – Storage of medicinal products

Medicinal products should be stored in an area that is clean and free from litter, dust and pests. Adequate precautions should be taken against spillage or breakage and cross contamination.

Appendices

Storage Procedure Appendix 13/01 - Rejected Products Log

Procedure

Medicinal products should be stored separately from other products and protected from harmful effects of light, temperature, moisture or other external factors.

Warehouse areas should be carefully maintained, ensuring that repair and maintenance operations do not present any hazard to the quality of the products.

There should be a system of stock rotation to ensure that oldest stock is sold first. Rotation of stock should be on a 'first expiry – first out' (FEFO) basis.

When newly received stock is being placed on the shelves, the existing stock should be checked to ensure it has adequate remaining shelf life. Older stock within its shelf life should be moved to the front of the picking face and the new stock put to the back.

Products beyond their expiry date should be immediately removed from saleable stock. They should be stored in the 'reject area' until such time as they can be returned to the supplier or destroyed.

Medicinal products with broken seals, damaged packaging or suspected of possible contamination should be withdrawn from saleable stock and stored in the reject area until such time as they can be destroyed.

All products stored in the reject area should be recorded to the Rejected Products Log (Appendix 13/01).

When the rejected product is removed from the reject area, this should also be recorded on the Rejected Products Log.

Rejected material should be destroyed in a timely manner. See in this guide SOP 21 'Waste Management of Medicinal Products'.

APPENDIX TO STORAGE PROCEDURE

Appendix 13/01 – Rejected Products Log

Rejected by and date	Product name	Product strength	Batch no.	Quantity	Reason	Removed by and date	Disposition by RP (R/D)*

* R (Returned to supplier), D (Destroyed)

17 STANDARD OPERATING PROCEDURE 14 – ORDER PROCESSING, PICKING AND DISPATCH

Introduction – Order processing, picking and dispatch

This procedure outlines the steps to be followed to ensure that the correct products ordered by the customer are selected, packed and delivered with no damage or errors.

Procedure

Picking and packing

Orders are received by telephone, fax or by other means.

Orders received by telephone are recorded manually so that a written record of the order is created.

The orders are transferred to warehouse personnel who will pick and assemble the order using the written record.

The picker must ensure that the correct product is picked (product name, strength and pack size).

The picker must ensure that the product has an appropriate shelf life remaining. It should be picked on a 'first expiry – first out' (FEFO) basis.

The batch number of the product should be recorded, where required, on the written record particularly if the product is being delivered to another branch of the company.

The picker should sign and date the picking record.

Before the order is invoiced or packed, it should be checked by another person. A record of this check should be made and the person checking the order should sign and date the picking record.

When medicinal products are transferred to another branch or supplied to another general sale wholesaler, the transaction is considered as a wholesale-to-wholesale transaction. As such, the batch numbers of the products being transferred are required to be recorded. See in this guide SOP 22 'Transfer of Medicinal Products Between Branches'.

Products should be packed in such a way to avoid breakage, contamination and theft. The packing should ensure that the required storage conditions of the products are maintained during transit.

Dispatch

Medicinal products should be transported to the customer in such a way that:
- Their identification is not lost.
- They do not contaminate, or are not contaminated by, other products or materials.

For each supply, a document containing the following information must be enclosed:
- Date of supply
- Name and pharmaceutical form of the product
- Expiry date
- Batch number (where required)
- Quantity supplied
- Name and address of the supplier
- Name and address of the consignee

Delivery drivers (including contract drivers) must be trained in the relevant areas of GDP.

Delivery vehicles must be suitable for transportation of medicinal products and prevent exposure of the products to conditions that could affect their quality or cause contamination.

Vehicles should be cleaned on a regular basis. Cleaning agents used should not have an adverse effect on the medicinal product quality. Record the cleaning on the Cleaning Record (Appendix 08/01). See in this guide SOP 08 'Cleaning Procedure'.

For transportation requirements, see in this guide SOP 23 'Transportation'.

18 STANDARD OPERATING PROCEDURE 15 – RETURN OF MEDICINAL PRODUCTS TO INVENTORY

Introduction – Return of medicinal products to inventory

This procedure describes the action to be taken when medicinal products are returned to the company by a customer for commercial reasons and not as a result of a quality complaint. Typical reasons for return are wrong delivery, overstocking, or products ordered in error. Products returned as a result of a quality complaint or issue should be managed through SOP 16 'Customer Complaints'.

Appendices

- Return of medicinal products to inventory Appendix 15/01 – Returned Medicinal Product Log
- Return of medicinal products to inventory Appendix 15/02 – Returned Product Assessment Form

Procedure

Customers should pre-notify the company that they wish to return a medicinal product.

When the returned product is received back into the premises it should be placed in a dedicated 'returns area', which is clearly labelled and in a temperature monitored area, until a decision on its disposition is made by the RP.

The details of the product should be recorded on the Returned Medicinal Products Log (Appendix 15/01).

Products can only be returned to saleable stock when the following conditions are met:
- Products are in the original unopened packs and in good condition.
- It is demonstrated that the products have been transported, stored and handled under proper conditions.
- The products have been returned within 10 days of delivery to the customer.
- The products have an acceptable shelf life remaining.
- It can be demonstrated that the products were originally purchased by the company (e.g. a copy of the original delivery docket is received with the returned products).
- There is no reason to believe that the products have been falsified.

Returned products must be examined and assessed by a sufficiently trained and competent person. This assessment should be recorded on the Returned Product Assessment Form (Appendix 15/02). The Returned Medicinal Products Log (Appendix 15/01) should be updated with the date of assessment and disposition of the product.

The RP must formally decide on the disposition of the product and record on Appendix 15/02 their decision to either return the product to saleable stock or reject the product.

If the product is rejected it must be transferred to the 'reject area' and recorded in Appendix 13/01 Rejected Products Log.

If the product is returned to saleable stock it must be entered onto the inventory management system.

The product should be returned to the pick face such that a 'first expiry – first out' (FEFO) system is operated.

Care should be taken that falsified medicinal product does not enter the legitimate supply chain through returns from customers. If returned product is suspected of being falsified, the RP should be notified immediately and the product must be placed in quarantine (see in this guide SOP 20 'Management of Falsified Medicinal Products').

APPENDICES TO PROCEDURE FOR RETURN OF MEDICINAL PRODUCTS TO INVENTORY

Appendix 15/01 – Returned Medicinal Products Log

Date product returned	Product name	Product strength	Batch no.	Quantity	Returned by	Removed by and date	Disposition by RP (S/R)*

* S (Saleable stock), R (Reject)

Appendix 15/02 – Returned Product Assessment Form

Date	Product name	Product strength	Batch no.	Expiry date	Quantity

Returned from:

Reason:

Date of original delivery to customer:
(must be within 10 days of receipt of return)

Acceptable shelf life remaining?	☐ Yes ☐ No
Products in original unopened pack?	☐ Yes ☐ No
Products in good condition?	☐ Yes ☐ No
Evidence that the product was transported, stored and handled under proper conditions?	☐ Yes ☐ No
Evidence that the product was originally supplied to the customer from the company (e.g. copy of delivery note attached)?	☐ Yes ☐ No
Reason to believe that product is/has been falsified?	☐ Yes ☐ No

Product assessed by: Date:

DISPOSITION:
(Return to Saleable Stock or Reject)

Approved by (RP): **Date:**

19 STANDARD OPERATING PROCEDURE 16 – CUSTOMER COMPLAINTS

Introduction – Customer complaints

All complaints and other information concerning potentially defective medicinal products must be collected and reviewed. The company must maintain a record of all customer complaints received relating to medicinal products involving issues of product quality, packaging and product distribution.

There should be a distinction made between complaints about the quality of a medicinal product and those relating to distribution.

Appendices

Customer Complaints Appendix 16/01 – Customer Complaint Form

Procedure

On receipt of a complaint from a customer, either relating to product quality or to the distribution service, it must be recorded on the Customer Complaints Form (Appendix 16/01).

If the complaint relates to the quality of a medicinal product, the RP must be informed immediately.

Complaints relating to product quality or problems with the primary packaging, i.e. container, cap, blister seal, carton, container label, should be directed to the primary distributor or product manufacturer. It must be ensured that acknowledgement of the complaint is received back from the distributor/manufacturer.

A complaint file should be opened for each customer complaint. All information relating to the complaint (as outlined in Appendix 16/01) should be recorded. Copies of all communications with the complainant, distributor and manufacturer must be maintained.

Arrangements must be communicated to the complainant for the return or collection of the product (where required). Samples to be returned to the primary distributor or product manufacturer should be carefully packaged to ensure the evidence that the product is defective is preserved so that the complaint can be adequately evaluated by the manufacturer. Care must be taken that any returned samples do not inadvertently get placed into saleable stock. Store in quarantine until dispatched back to the manufacturer/distributor.

It may be necessary, on receipt of information from the manufacturer/distributor, to quarantine remaining packs of the product/batch held in stock pending further investigation. If this is required, physically remove all affected stock to the quarantine location and complete the Quarantine Log (Appendix 10/01). See in this guide SOP 10 ‘Receipt of Medicinal Products’.

In some cases, a recall of the product may result from the investigation of the customer complaint by the manufacturer. Refer to SOP 17 'Recall Procedure' if a recall is required.

A response must be sent to the complainant. This is usually performed by the primary distributor or manufacturer. The company should request a copy of the correspondence.

The RP should sign and date the Customer Complaint Form upon completion.

APPENDIX TO CUSTOMER COMPLAINTS PROCEDURE

Appendix 16/01 – Customer Complaint Form

Date:
Complaint recorded by:
Type of complaint: ☐ Medical product quality ☐ Distribution
Received from:
Address:
Contact details:

DISTRIBUTION COMPLAINT	
Nature of complaint:	
Corrective action taken:	
Approved by (RP):	
Date closed:	

MEDICINAL PRODUCT QUALITY COMPLAINT (please complete the following)	
Product name, strength and pack size:	
Batch no.:	
Expiry date:	
PA no.:	
Quantity:	
Nature of complaint:	
Date RP notified:	
Action taken:	
Date manufacturer/ supplier notified:	
Date acknowledgement from manufacturer/ supplier received:	
Sample requested:	☐ Yes ☐ No
Date sample sent:	
Date response received from manufacturer/ supplier:	
Date response sent to complainant:	

Complaint closed out by (RP): Date:

20 STANDARD OPERATING PROCEDURE 17 – RECALL PROCEDURE

Introduction – Recall procedure

A wholesaler should be able to conduct a recall of medicinal products if required. A recall may be defined as the retrieval from the marketplace of a batch(es) of any medicinal products which are the subject of a quality defect, another non-compliance with the product authorisation or a safety or efficacy issue. The purpose of a batch or product recall is to minimise the risk to public health.

A quality defect may be defined as an attribute of a medicinal product or component which may affect the quality, safety and/or efficacy of the product and/or which is not in line with the approved product authorisation.

There are different types of recalls and these are detailed in the Classification of Recall Listing (Appendix 17/02). It is expected that no recall actions are taken without prior agreement with the HPRA.

Further information on recalls is detailed in the HPRA's 'Guide to Recall of Medicinal Products for Human and Veterinary Use'.

The contact details for the personnel at the company, particularly the RP, and for the HPRA should be documented within the procedure using the Contact Details Form (Appendix 17/01). A copy of the recall procedure should be forwarded to the Compliance department of the HPRA following any changes to personnel listed in Appendix 17/01.

Appendices

- Recall Procedure Appendix 17/01 – Contact Details Form
- Recall Procedure Appendix 17/02 – Classification of Recall Listing
- Recall Procedure Appendix 17/03 – Medicinal Product Recall Log
- Recall Procedure Appendix 17/04 – Medicinal Product Recall Record

Procedure for notification of a recall

Where the company is notified of a recall

Recall notifications may be issued by the supplier, the PA holder, the manufacturer or occasionally by the HPRA. The RP should be notified immediately of all recall notifications received. The letter should indicate that the recall actions have been agreed with the HPRA. The actions specified in the recall letter should be performed without delay. In these situations, the role of the company is generally restricted to:

- physically quarantining stock of the batch(es) on hand

- where instructed to do so, notifying relevant customers of the recall action and the actions specified in the recall letter for those customers to take
- where instructed to do so, receiving back and physically quarantining the recalled stock from customers
- transporting the quarantined stock back to the supplier

The RP should read the recall notification carefully and follow the instructions provided. The recall notification will specify the product details, batch number(s), batch details and the expiry dates concerned. Use the Medicinal Product Recall Log (Appendix 17/03) to record the initial details of the recall. The company should review goods inwards records/supplier documentation to identify if the product or batch(es) were received from the supplier. A member of staff should go to the warehouse and check all locations for the concerned product (goods inwards, bulk storage areas, pick face, quarantine area, returned area, reject area). If stock is identified in the warehouse, it should be removed from the shelves and stored in a quarantine area. This should be recorded on the Quarantine Log (Appendix 10/01).

If the company determines that it has been supplied with the medicinal product or it has stock of the medicinal product, the Medicinal Product Recall Record (Appendix 17/04) should be used to record the initial details of the recall.

The following actions may be requested in the recall notification. Read the recall notification carefully before taking any actions.

1. Ensuring that customers are notified:

If the recall notification requests that the product should be recalled from customers, use delivery dockets/invoices issued by the company to identity customers/recipients that may have received that product. The company should also check whether the product was supplied to another branch or other general sale wholesaler. A copy of this list of customers (including wholesale customers) and a copy of all delivery dockets/invoices should be maintained. Record all details on record the Medicinal Product Recall Record (Appendix 17/04).

Contact the recipients/customers if directed in the recall notification. If it is necessary to forward customers a copy of the recall notification, this will be specified in the recall notification.

2. Receiving and quarantining recalled stock back from customers:

Recalled product that is received back from customers should be placed in the same quarantine area as products removed from the shelf. Check that each customer has returned the same quantity of product as recorded in the company invoices/delivery dockets. Where there is a discrepancy, contact the customer for verification. When all recalled product has been received back from all customers, a reconciliation should be performed to determine the effectiveness of the actions taken as part of the recall.

The following should be recorded on Medicinal Product Recall Record (Appendix 17/04):
- the number of packs of the recalled product/batch(es) which were held in stock when the recall was initiated
- the number of packs returned to the company from customers
- a calculation of the total number of packs of each batch received back as a percentage of the total number of packs of each batch distributed (this is the % reconciliation)
- any stock unaccounted for

The completed Medicinal Product Recall Record should be signed by the RP and sent to the supplier or manufacturer or the HPRA (as requested). A copy of the record should be retained.

3. Transporting the quarantined stock back to the supplier:

The company may wish to contact the supplier to arrange replacement stock for the recalled product and/or to get credit for any stock returned to the supplier.

Where a quality defect is identified at the company premises but did not occur at the premises

In the event that a quality defect or suspected quality defect is identified at the premises, the RP should be notified immediately. The RP should review the circumstances surrounding the quality defect or suspected quality defect. If it is determined that the quality defect did not occur at the premises, the company should immediately contact its supplier. In this situation, the company is not responsible for co-ordinating the investigation or potential recall and should await further instruction before taking any actions.

These activities should be recorded on the Medicinal Product Recall Record (Appendix 17/04).

If a recall action is necessary, the company should follow the steps in section 20.3.1 of this guide.

Where the quality defect occurs at the company premises

In the event that a quality defect or suspected quality defect occurs while the stock is under the company's control, the RP should be notified immediately. The RP should immediately contact the HPRA's Quality Defects and Recall section with reference to the HPRA's 'Guide to Recall of Medicinal Products for Human and Veterinary Use'. In this situation, the company is responsible for co-ordinating the investigation or recall.

These activities should be recorded on the Medicinal Product Recall Record (Appendix 17/04).

The company should not take any recall actions without prior agreement with the HPRA. Where a recall action on the Irish market is agreed, the recall letter must be prepared by the company

and approved by the HPRA in advance of issuance. The company should follow the steps in section 20.3.1 of this guide.

Maintaining the recall procedure up to date

A mock recall should be performed at least annually to test the recall procedure. There is no need to contact customers or to return stock during this mock recall. The mock recall should be carried out to confirm that a product can be traced from receipt, to stock and to customer. Mock recalls should take account of the complexity of wholesaler operations and should be carried out on a risk basis. Where the mock recall identifies gaps in the process that could lead to an ineffective recall in a true recall scenario, those gaps should be appropriately addressed in a justified time period, e.g. 30 days, and the recall procedure revised accordingly. Copies of supplier documentation and delivery dockets used in the mock recall should be maintained for a minimum for five years.

APPENDICES TO RECALL PROCEDURE

Appendix 17/01 – Contact Details

The 24-hour contact details of the RP and one other person (for holiday cover and sick leave) must be maintained. These are:

Name of RP:	**Name of other:**
Phone no:	Phone no:
Mobile no:	Mobile no:
Fax no:	Fax no:

The 24-hour contact details of the HPRA are listed on the HPRA website.

Correspondence by email should be used, where possible, to report suspected and confirmed quality defect issues to the HPRA.

Email: qualitydefects@hpra.ie

Post: Compliance Department - Quality Defects
Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
D02 XP77

Telephone numbers:

Emergency out-of-office hours (urgent issues only): +353 1 6343560

Ms. Lisa Byrne, Market Surveillance Manager (Acting)
Office contact no.: +353-1-6764971
Out-of-hours contact no.: +353-86-8391955)

Ms. Michelle Cuffe, Quality Defects and Recall Manager
Office contact no.: +353-1-6764971
Out-of-hours contact no.: +353-86-0083221 (mobile)

Ms. Breda Gleeson, Market Compliance Inspector
Office contact no.: +353-1-6764971
Out-of-hours contact details: +353-87-9703559 (mobile)

Ms. Anne Hayes, Director of Compliance (Interim)
Office contact no.: +353-1-6764971
Out-of-hours contact details: +353- 86-2372242 (mobile)

Appendix 17/02 – Classification of Recall

There are three classes of a recall depending on the level of seriousness of the issue. There is also a 'Caution-In-Use Notification' (CIUN). This is used where the nature of the product defect does not require a recall but there is a need to alert healthcare professionals to the details of the defect.

A summary of the different classes and their requirements is listed in the table below:

Recall classification	**Class I**	**Class II**	**Class III**	**Caution In Use**
Notification period	Within 24 hours	Within 72 hours	Within 5 days	Within 5 days
Notification method	Phone and fax, radio/TV (if necessary), press announcements followed by letter	Letter/fax if necessary, followed by phone (if necessary)	Letter/fax (if necessary)	Letter
Notification extent	Wholesalers and other retailers	Wholesalers and other retailers	Wholesalers and other retailers	Possibly wholesalers
Retrieval method	Direct uplift of stock	Via wholesaler	Via wholesaler	Not applicable

Appendix 17/03 – Medicinal Product Recall Log

Notification receipt date	Product name	Product strength	Product form*	Batch no(s)	PA number	Expiry date	Product distributed (Y/N)	Date recall closed	Entry by

* e.g. tablets, sachets, powder

Appendix 17/04 – Medicinal Product Recall Record

I. Details of the Recall	
Product name	
Product strength	
Product form (e.g. tablets, sachets, powder)	
Product packaging (e.g. tablets in a tub, blisters in a carton)	
Batch no(s)	
Expiry date	
PA number	
Name of the marketing authorisation holder	
Reason for recall	
Classification of recall	
Level of recall (e.g. to wholesale level, to retail level, to consumer level)	
Supplier details	
Total quantity received from supplier for each batch	
Total quantity distributed for each batch	
Cause of the quality defect (Note this only applies if the recall action was taken as a result of an error that occurred at the company)	
Specific corrective actions to be implemented by the company addressing the issue which led to the recall. (Note this only applies if the recall action was taken as a result of an error that occurred at the company.)	
Section I completed by: **Date:**	

II. Results of the Recall – Reconciliation	
(a) Number of packs of recalled product received from supplier	
(b) Number of packs of recalled product in stock	

(c) Number of packs of recalled product distributed	
(d) Number of packs of recalled product received back from customers	
(e) Number of packs of recalled product not returned	
Percentage of packs reconciled (i.e. number of packs received back as a % of the number of packs distributed) **(d)/(c) x 100**	
Unaccounted stock **(b) – {(a)– (c)}**	
Section II completed by: **Date:**	
III. Chronological Account of the Recall	
Date quality defect identified	
Date quality defect reported to supplier/HPRA	
Date of approval of recall notification by the HPRA	
Date recall notification received	
Date of quarantining of stock held	
Dates within which recalled packs were received back from customers	
Dates within which recalled packs received back from customers was quarantined	
Date of closing the recall on site	
Date of sending Recall Report to the supplier/manufacturer/HPRA	
Section III completed by: **Date:**	

Report reviewed by (RP): Date:

21 STANDARD OPERATING PROCEDURE 18 – OUTSOURCED ACTIVITIES

Introduction – Outsourced activities

Certain activities relating to wholesaling of medicinal products may be outsourced. However, the responsibility for these activities remains with the authorised company. A system should be in place to control and review any outsourced activities relating to the wholesaling of medicinal products to ensure they are conducted in a manner that is complaint with GDP.

Appendices

Outsourced Activities Appendix 18/01 – Outsourced Activity Log

Procedure

Qualifying companies to conduct outsourced activities

All outsourced activities should be clearly defined, agreed and controlled. Examples of outsourced activities may include the preventative pest control programme, the maintenance of temperature control in the warehouse and transportation providers.

When a company decides to outsource any activities relating to the wholesaling of medicinal products, it should assess the competence of the company to successfully conduct the outsourced activity. This should include either an on-site audit or a paper-based audit, and a verification of the company's authority if necessary. A contract should be in place with the contracted company to define the duties of each party. The contract should include a commitment from the contracted company to the following:

- Activities will not be subcontracted without prior approval by the authorised company.
- It will refrain from any activity which may adversely affect the quality of the medicinal products.
- It must forward any information that may influence the quality of the medicinal products within defined timelines.
- For transportation providers, the requirements listed in the procedure covering transportation need to be included.

The audit of the company and the contract should be approved by the RP prior to the commencement of activities. Once a company is approved by the RP it should be added to Appendix 18/01 – Outsourced Activity Log.

Communication

Where the contracted company recommends that the authorised company performs corrective actions to address certain issues, the authorised company should record completion of these corrective actions. The completion of these actions should be signed off by the RP.

Review of companies conducting outsourced activities

The company should maintain a list of all the companies that conduct activities on their behalf. Appendix 18/01 – Outsourced Activity Log can be used to document this. Each company on this list should be audited on a periodic basis and the contract in place reviewed. The frequency of this review should be determined by the risk the contractor presents to medicinal product quality, and should be documented in Appendix 18/01 – Outsourced Activity Log. In addition, audits should be conducted and contracts reviewed whenever there is a change to the activity being conducted.

APPENDIX TO OUTSOURCED ACTIVITIES PROCEDURE

Appendix 18/01 – Outsourced Activity Log

Name of company conducting outsourced activity	Description of outsourced activity	Date of initial approval	Approved by (RP) and date	Date of last review	Date of next review

22 STANDARD OPERATING PROCEDURE 19 – SELF-INSPECTIONS

Introduction – Self-inspections

Self-inspections should be conducted and documented to monitor the implementation of, and compliance with, GDP principles and to propose any necessary corrective actions. They also ensure compliance with the requirements of the quality system (e.g. ensure logbooks and records are being maintained correctly).

Appendices

Self-inspection Appendix 19/01 – Self-inspection Record Form

Procedure

A self-inspection programme should be in place, and this should cover all aspects of GDP and compliance with regulations, guidelines and operating procedures.

The self-inspection should be performed at least annually.

The self-inspection team should be comprised of the RP and one other staff member who ideally is not connected with the area being audited.

The self-inspection team must review the outcome of the previous inspection before commencing to determine whether the corrective actions have been implemented.

Use the Self-inspection Record Form (Appendix 19/01) to record any observations or deficiencies identified. The cause(s) of the observation and deficiencies should also be recorded.

Proposed corrective actions should be recorded on the form with a proposed timeline for implementation of the corrective action.

This should be reviewed on a monthly basis to ensure all corrective actions have been implemented. Verify that each corrective action has been carried out by completing a ‘yes’ or ‘no’ in the associated column of Appendix 19/01.

The self-inspection cannot be closed off (signed by the RP) until all corrective actions have been implemented.

APPENDIX TO SELF-INSPECTION PROCEDURE

Appendix 19/01 – Self-inspection Record Form

Date of self-inspection: _____ Performed by: _____

Previous self-inspection record form reviewed? ☐ Yes ☐ No

Area	Examples	Observations	Cause(s)	Corrective action	Timeline for completion	Corrective action performed?
Quality management	Are the deviations log and change control log up to date? Have records been completed for deviations, change control and risk assessments? Have all issues been closed off? Has a management review been completed?					☐ Yes ☐ No
Personnel	Booster training provided to all personnel? All training records completed correctly? Have contracted drivers been trained?					☐ Yes ☐ No
Documentation	Have SOPs been reviewed? Any new SOPs issued in the year?					☐ Yes ☐ No

Area	Examples	Observations	Cause(s)	Corrective action	Timeline for completion	Corrective action performed?
	- Have relevant personnel been trained on these? - Are index/distribution/revision forms up to date? Is the correct SOP version in use? Have all records (cleaning, temperature, etc.) been completed correctly and reviewed where necessary? Is the information on the wholesaler's authorisation up to date?					
Premises/ storage	Check the pick face for expired, damaged, incorrect stock. Check pest control records - no. of visits up to date? Has temperature mapping or a risk assessment of the storage area been completed? Have temperature-monitoring probes been calibrated? Check status of products in quarantine/reject areas. Are these recorded on the correct forms?					☐ Yes ☐ No

Area	Examples	Observations	Cause(s)	Corrective action	Timeline for completion	Corrective action performed?
	Observe products being checked in and put away – is this in accordance with SOPs?					
Approval of suppliers	Are there wholesaler's or manufacturer's authorisations on file for all suppliers? Are all GDP/GMP certificates on file? Are these up to date?					☐ Yes ☐ No
Order processing, picking and dispatch	Observe the picking of an order: - Is it in accordance with SOP? - Are the records being signed and correct information recorded? - Is order checked before dispatch? Check the cleanliness of the delivery vehicles.					☐ Yes ☐ No
Transfer between branches	Was there transfer of medicinal products between branches? Were these recorded correctly (batch numbers)?					☐ Yes ☐ No
Waste management	Check the status of products in the reject area - are these recorded in the Rejected Products Log? Can they be disposed of?					☐ Yes ☐ No
Return of medicinal products to inventory	Are goods checked before return to stock? Review Returns Assessment Forms - Are they completed correctly?					☐ Yes ☐ No

Area	Examples	Observations	Cause(s)	Corrective action	Timeline for completion	Corrective action performed?
	Observe processing of a returned medicinal product – is this in accordance with SOP? Check status of products in returns area.					
Recall procedure	Has a mock recall been performed? Was it in accordance with SOP? Are the contact details up to date?					☐ Yes ☐ No
Customer complaints	Have there been any customer complaints? Were the records completed correctly? Was a reply received from the supplier? Was the complaint answered/closed out?					☐ Yes ☐ No
Falsified medicinal products	Were there any suspected falsified products received/identified? Were there any suspicious orders/requests? Were these notified to the HPRA?					☐ Yes ☐ No
Self-inspection	Has a self-inspection been performed in the last year? If not, why? Were all corrective actions identified implemented? If training was required as a corrective action, was this performed and recorded? Was the self-inspection closed out?					☐ Yes ☐ No

Area	Examples	Observations	Cause(s)	Corrective action	Timeline for completion	Corrective action performed?
Outsourced activities	Is there an up-to-date list of outsourced activities? Has there been a recent assessment of the companies? Are all contracts up to date?					☐ Yes ☐ No
Transportation	Are all drivers trained in GDP? Have all transportation issues been investigated? Are vehicles clean and in good condition? Are medicines appropriately packed? Is all documentation included with each order?					☐ Yes ☐ No

Self-inspection reviewed and closed out by (RP): Date:

23 STANDARD OPERATING PROCEDURE 20 – MANAGEMENT OF FALSIFIED MEDICINAL PRODUCTS

Introduction – Management of falsified medicinal products

It is imperative that all wholesalers operate using good governance and display vigilance in their efforts to prevent falsified medicinal products from being placed on the market. Wholesalers should be aware of the possibility of falsified medicinal products being supplied inadvertently through the legitimate supply chain.

A falsified medicinal product is any medicinal product with a false representation of:

a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;
b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or
c) its history, including the records and documents relating to the distribution channels used.

This definition does not include unintentional quality defects and is without prejudice.

Actively ensuring the legitimacy of suppliers (see in this guide SOP 11 'Establishing the Authority of Suppliers to Supply Medicinal Products') and maintaining a list of approved suppliers (Appendix 11/01), as well as being familiar with the history of the supply chain for the products received and with the appearance of the packaging of the products will minimise the risk of falsified products entering the supply chain.

Staff should be trained to be aware of falsified products especially the possibility of such products entering the supply chain through the returned products route.

Wholesalers should never allow their wholesaler's authorisation to be used by a third party to source product and should be wary of suppliers offering excessive discounts on price or quantities.

Any suspicious approaches or activities noticed by the wholesaler should be reported to the HPRA.

When it is discovered, or the wholesaler is informed, that falsified medicines have been supplied, then the falsified product must be removed from the marketplace quickly and effectively to minimise the risk to public health.

A wholesaler in possession of a product that is found to be (or suspected of being) falsified is responsible for the removal of that product from saleable stock. If the wholesaler is suspicious that a product is not genuine, then the HPRA and the marketing authorisation holder should be contacted immediately.

The wholesaler may also be notified of a falsified medicinal product which does not impact immediately on their business. In such situations, details of the notification should be recorded and used at goods inwards checks.

Appendices

- Management of Falsified Medicinal Products Appendix 20/01 – Falsified Medicinal Product Notification Log
- Management of Falsified Medicinal Products Appendix 20/02 – Falsified Medicinal Product Record Form

Procedure for notification of a falsified product

Where the company is notified of a falsified (or suspected falsified) medicinal product

Notification may be provided to the company by the supplier, the HPRA, the PA holder or the manufacturer. In these situations, the role of the company is generally restricted to:
- quarantining stock of the batch(es) on hand
- ensuring that customers are notified
- receiving and quarantining the falsified stock back from customers
- transporting the quarantined stock back to the supplier
- making a record of the falsified notification for future goods inwards checks

The company should follow the instructions supplied by either the PA holder, manufacturer, supplier or the HPRA.

It is the responsibility of the RP to ensure that these requirements are met.

On being informed that the company has (or may have) received falsified (or suspected falsified) medicinal products, the company should:
- First ascertain whether the products were actually received by them.
- Log the notification in the Falsified Medicinal Product Notification Log (Appendix 20/01).
- Check goods inwards documentation and products physically on the shelf.
- If it is determined that the company did receive the affected products, SOP 17 'Recall Procedure' should be initiated immediately and appropriate personnel must be notified. Follow the Recall Procedure with respect to quarantining the stock on hand and recording all activities.

Where the company identifies falsified (or suspected falsified) medicinal products at its premises

In the event that a falsified (or suspected falsified) medicinal product is identified at the company, then the RP should immediately be notified.

- The RP should go to the warehouse and check all locations for the concerned product (goods inwards, bulk storage areas, pick face, quarantine area, returned area, and reject area). Delivery vehicles should also be checked.
- The RP should ensure that the affected product/batch is removed and stored in a quarantine area, labelled as falsified product.
- The RP should ensure that any returned medicinal product received back from customers during this time is checked to determine whether it may be the affected product.
- The RP should contact the supplier and the HPRA immediately, noting the PA number and batch number(s) of the product affected.

These activities should be recorded in the Falsified Medicinal Product Record Form (Appendix 20/02).

The response of the HPRA or supplier should be awaited.

If it is confirmed that the product is falsified, SOP 17 'Recall Procedure' should be initiated immediately.

General

The company may wish to contact the supplier to arrange replacement stock for the product and/or to get credit for any stock returned to the supplier.

Falsified stock should be destroyed in consultation with the HPRA.

APPENDIX TO MANAGEMENT OF FALSIFIED MEDICINAL PRODUCTS PROCEDURE

Appendix 20/01 – Falsified Medicinal Product Notification Log

Notification receipt date	Product name	Product strength	Product form*	Batch no(s)	PA no.	Expiry date	Identifying comments	Entry by

* e.g. tablets, sachets, powder

Appendix 20/02 – Falsified Medicinal Product Form

Product name	
Product strength	
Product form (e.g. tablets, sachets, powder)	
Description of packaged product (e.g. tablets in a tub, blisters in a carton)	
Batch no(s)	
Expiry date	
PA number	
Received from	
Date received	
Total quantity of packs received from supplier for each batch	
Date falsified or suspected falsified product identified on site	
Date of quarantining of stock held	
Dates HPRA and supplier/PA holder notified	
Date confirmation received back from HPRA/supplier/PA Holder	
Date of initiation of recall	
Completed by: **Date:**	

Report reviewed by (RP): Date:

24 STANDARD OPERATING PROCEDURE 21 – WASTE MANAGEMENT OF MEDICINAL PRODUCTS

Introduction – Waste management of medicinal products

All returned (and rejected), rejected or recalled products (if instructed) should be destroyed within an appropriate and manner and in accordance with waste legislation. The decision to dispose of products should be documented and recorded.

The use of third-party contractors should be managed by a service level agreement/contract (see in this guide SOP 18 'Outsourced Activities').

Procedure

All medicinal products which have been rejected should be stored in the 'rejects area'.

Details of the products should be recorded in the Rejected Products Log (Appendix 13/01) (see in this guide SOP 13 'Storage of Medicinal Products').

Medicinal Products should be disposed of by an authorised service provider within a justified time period and stocks of rejected products should not build up on site. There should be a contract in place with the disposal company/service provider if outsourced.

When the products are removed from the premises for disposal, the date of this activity should be recorded in the Rejected Products Log (Appendix 13/01).

The RP must be involved in the decision to send products for disposal.

Records and certificates of destruction should be received back from the disposal company and maintained.

25 STANDARD OPERATING PROCEDURE 22 – TRANSFER OF MEDICINAL PRODUCTS BETWEEN BRANCHES

Introduction – Transfer of medicinal products between branches

When medicinal products are transferred between branches or supplied to another general sale wholesaler, the transaction is considered as a wholesale-to-wholesale transaction. As such, the batch numbers of the products being transferred are required to be recorded. See in this guide SOP '14 'Order Processing, Picking and Dispatch'.

Appendices

Transfer of Medicinal Products between Branches Appendix 22/01 - Approved Wholesale Customer List.

Procedure

New wholesale customers

When supplying another branch (or another general sale wholesaler) with medicinal products the company should first request a copy of their wholesaler's authorisation and a copy of the most recently issued GDP certificate. Use the HPRA or the EudraGMDP website to check the status of the supplier against the list of authorised wholesalers and obtain a printout of the web page. It is important to review the content and detail of each authorisation including the addresses listed and the categories of medicinal products listed on the authorisation.

Use the Approved Wholesale Customer List (Appendix 22/01) to record the details of the customer.

If the wholesale customer uses a third party on their behalf or if other parties are involved in the supply chain of their products, details of these arrangements should be recorded on Appendix 22/01.

The RP must be involved in the approval of new wholesale customers.

Medicinal products should only be dispatched to another branch (or another general sale wholesaler) for whom a wholesaler's authorisation has been received and a GDP certificate has been received.

Existing wholesale customers

At least annually, the authorised status of all wholesale customers should be reviewed.

This can be done by checking the status of the wholesale customer against the list of authorised wholesalers on the HPRA website and obtaining a printout.

- If it is found that the wholesale customer is no longer listed as an authorised wholesaler, notify the RP.
- If it is determined that the wholesale customer is no longer authorised, they must be removed from the Approved Wholesale Customer List (Appendix 22/01). An updated copy of the list should be given to dispatch personnel.
- No medicinal products should be supplied to that wholesale customer.

Records of supply to wholesale customers

The batch number of the product must be recorded on the picking record or delivery docket or invoice (or electronically).

If more than one batch of the product is being supplied, the quantity of each batch must be specified on the relevant record.

Medicinal products should not be supplied to another general sale wholesaler until a copy of their wholesaler's authorisation is obtained and their authority to receive the products has been verified.

Appendix 22/01 – Approved Wholesale Customer List

Wholesale customer name:	Wholesale customer address:	Other supply chain parties:	Copy of wholesale authorisation and GDP certificate on file:
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
Customers approved by (RP): **Date:**			

26 STANDARD OPERATING PROCEDURE 23 – TRANSPORTATION

Introduction – Transportation

Medicinal products must be protected against breakage, adulteration and theft during transportation. In addition, temperature conditions should be maintained within acceptable limited during transportation. Monitoring of temperatures during transportation using calibrated measuring devices in necessary to provide assurance that conditions are under control.

Procedure

Transportation

The company should document the required storage conditions for the medicinal products that it is transporting in the 'Approved Supplier List' (Appendix 11/01). Giving consideration to this, the company should then document and plan out the delivery routes for medicinal products.

The company should be able to demonstrate that medicines have not been exposed to conditions that may compromise their quality and integrity. The company should conduct a seasonal transport temperature validation study using an appropriate route (e.g. longest distance travelled on delivery route) or alternatively perform a risk assessment of the planned delivery routes to determine where temperature controls are required. In general, temperature monitoring data should be used to support this risk assessment. If vehicles require permanent temperature monitoring devices these should be maintained and calibrated annually as described in SOP 12 'Temperature Mapping and Monitoring'.

The company must ensure that products are not stored for prolonged periods during transportation and should endeavour to transport medicinal products as efficiently as possible. It is the position of the HPRA that periods of storage longer than 48 hours during transportation would be defined as storage requiring that premises to hold a wholesaler's authorisation.

Drivers should be trained in the requirements of GDP. This should be conducted as described in SOP 7 'Training'.

Medicinal products should be packed in containers that protect them from damage and external influences. Containers must not adversely affect the product quality. The documentation that should accompany the products is described in SOP 14 'Order Processing, Picking and Dispatch'. Vehicles must undergo regular maintenance including cleaning and safety precautions.

Deliveries of medicinal products must be made to the address stated on the delivery note and into the care of the customer.

Deviation during transportation

Any deviations in the planned transportation should be reported to the RP within defined timeframes. Examples of these deviations include:

- Temperature excursions
- Product damage
- Non-delivery to the customer
- Diversion from planned route
- Accident/breakdown
- Theft
- Emergency deliveries outside of hours

The RP should raise a deviation and should follow the process described in SOP 03 'Deviations'.

Outsourced transportation activities

Where the company employs an external company to conduct transportation activities, an audit must be conducted to ensure they meet the requirements and a contract agreement must be in place as detailed in SOP 18 'Outsourced Activities'.

27 CONTACT DETAILS

For further information contact:
Compliance Department
Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
D02 XP77

Telephone: +353-1-6767836
Email: compliance@hpra.ie